LEXSEE 52 F.3D 1043

GLAXO INC. and GLAXO GROUP LIMITED, Plaintiffs-Appellees, v. NOVOPHARM LTD., Defendant-Appellant. GLAXO INC. and GLAXO GROUP LIMITED, Plaintiffs-Appellees, v. NOVOPHARM LTD., Defendant-Appellant.

94-1026, 94-1026

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

52 F.3d 1043; 1995 U.S. App. LEXIS 9070; 34 U.S.P.Q.2D (BNA) 1565

April 21, 1995, Decided

SUBSEQUENT HISTORY: [1]**

Rehearing Denied and In Banc Suggestion Declined June 21, 1995, Reported at: *1995 U.S. App. LEXIS 16625.*

PRIOR HISTORY: Appealed from: U.S. District Court for the Eastern District of North Carolina Judge Boyle.

DISPOSITION: AFFIRMED

COUNSEL: Stephen B. Judlowe, Hopgood, Calimafde, Kalil, Blaustein & Judlowe, of New York, New York, argued for plaintiffs-appellees. With him on the brief were William G. Todd and Janet B. Linn. Also on the brief were Steven P. Lockman, Arnold & Porter, of Washington, D.C. and Joseph W. Eason, Moore & Van Allen, of Raleigh, North Carolina, of counsel.

Robert F. Green, Leydig, Voit & Mayer, LTD., of Chicago, Illinois, argued for defendant-appellant. With him on the brief were John E. Rosenquist and Jeffrey S. Ward.

JUDGES: Before ARCHER, Chief Judge, RICH, and MAYER, Circuit Judges. Opinion for the court filed by Circuit Judge RICH. Dissenting opinion filed by Circuit Judge MAYER.

OPINIONBY: RICH

OPINION: [*1045] RICH, Circuit Judge.

Novopharm Ltd. (Novopharm) appeals the judgment of the United States District Court for the Eastern District of North Carolina, *Glaxo, Inc. v. Novopharm Ltd., 830 F. Supp. 871, 29 U.S.P.Q.2D (BNA) 1126 (E.D.N.C. 1993),* that United States Patent No. 4,521,431 was not invalid and was infringed, and enjoining Novopharm from the commercial manufacture or sale of the patented **[**2]** crystalline form of ranitidine hydrochloride. We affirm.

Background

Glaxo Inc. and Glaxo Group Ltd. (collectively Glaxo) are the owner and exclusive United States licensee, respectively, of United States Patent No. 4,521,431 ('431 patent). The '431 patent claims a specific crystalline form of the compound ranitidine hydrochloride, designated as "Form 2," which Glaxo markets as an antiulcer medication under the brand name Zantac. n1 The '431 patent issued on June 4, 1985.

n1 Claims 1 and 2 of the '431 patent, in issue here, read:

> 1. Form 2 ranitidine hydrochloride characterised by an infra-red spectrum as a mull in mineral oil showing the following main peaks: [list of peaks]
>
> 2. Form 2 ranitidine hydrochloride according to claim 1 further characterised by the following x-ray powder diffraction pattern expressed in terms of "d" spacings and relative intensities (l) (s=strong, m=medium, w=weak, v=very, d=diffuse) and obtained by the Debye Scherrer method in a 114.6 mm diameter camera by exposure for 12 hours to CoKa radia-

tion and for 3 hours to CuKa radiation: [table]

The '431 patent also claims various pharmaceutical compositions and methods of using Form 2 ranitidine hydrochloride. These claims are not at issue in this case.

[**3]

In 1976, Glaxo chemists investigating potential antiulcer medications synthesized an aminoalkyl furan derivative, later named ranitidine, [*1046] which proved to be a potent histamine blocker, inhibiting the secretion of stomach acid. Later that year, Glaxo filed an application for a patent on ranitidine in the United Kingdom. It followed with an application for a United States patent, which issued as No. 4,128,658 ('658 patent) on December 5, 1978. The '658 patent claims a number of structurally similar compounds, including ranitidine and its hydrochloride salt. It discloses one method for preparing ranitidine hydrochloride, set forth in the '658 patent as Example 32. n2

n2 Developed by Glaxo's David Collin in June 1977, that method involves dissolving ranitidine in industrial methylated spirit containing dissolved hydrogen chloride gas. Ethyl acetate is added to the solution, and ranitidine hydrochloride precipitates from solution as a crystalline solid characterized by a melting point of 133-134DegreesC.

Glaxo prepared [**4] large quantities of ranitidine hydrochloride between 1977 and 1980 for use in toxicology and clinical studies. Instead of using the process of Example 32, however, Glaxo's chemists prepared this material using a similar process that they labelled Process 3A. They later developed a more efficient method that they called Process 3B. Until April 15, 1980, both Process 3A and Process 3B yielded ranitidine hydrochloride identical in all respects to that originally produced using the Example 32 procedure.

On that date, however, Glaxo's Derek Crookes used Process 3B to prepare crystalline ranitidine hydrochloride that was visibly different from all previous batches of the salt. The difference was confirmed by infra-red (IR) spectroscopy and x-ray powder diffraction, which revealed that the new product was a crystalline form, or polymorph, of ranitidine hydrochloride that differed from the previously known form. Glaxo began to refer to this new polymorph as Form 2 ranitidine hydrochloride (designating the old polymorph as Form 1).

Because Form 2 had better filtration and drying properties, making it better suited for commercial applications, Glaxo decided to proceed with commercialization [**5] of Form 2 rather than Form 1. Form 2 was hampered by poor flow properties, however, which made the material difficult to measure and dispense in its pure form. Accordingly, Glaxo scientists developed a novel azeotroping process n3 to granulate the Form 2 salt, which made it much easier to make into pharmaceutical compositions. This process was the subject of a British patent application that Glaxo eventually abandoned without disclosing the process to the public.

n3 Azeotroping is a technique for separating a chemical mixture, the components of which would otherwise be difficult to separate because of the similarity of their boiling points. An additional substance is added to the mixture, selected for its ability to interact with a component of the original mixture to form an azeotrope -- a mixture of substances "the composition of which does not change upon distillation." See McGraw-Hill Dictionary of Scientific and Technical Terms 162 (4th ed. 1989). If the proper substance is selected, the resulting azeotrope will have a boiling point that differs substantially from the desired component of the original mixture. The desired component can then be successfully separated from the azeotrope by distillation. See Hawley's Condensed Chemical Dictionary 109 (11th ed. 1987).

[**6]

Glaxo filed a patent application covering Form 2 ranitidine hydrochloride in the United Kingdom on October 1, 1980. It filed a United States application thereon the next year, which eventually issued as the '431 patent in suit. When George Graham Brereton, Glaxo's patent officer initially charged with pursuing the United States application, learned of the azeotropic granulation process and Glaxo's desire to keep that process secret, he recommended that Glaxo not claim pharmaceutical compositions of the Form 2 salt for fear of violating the best mode requirement. Brereton apparently believed that disclosure of the azeotroping process would be necessary because it was the best way to make the Form 2 salt for use in preparing pharmaceutical compositions. He later moved to another position at Glaxo. The U.S. application was eventually amended to include pharmaceutical composition claims, but Glaxo did not amend the specification to disclose the azeotroping process.

On August 9, 1991, Novopharm Ltd. filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration [*1047] (FDA), seeking FDA

approval to manufacture and sell a generic version of Form 2 ranitidine hydrochloride **[**7]** beginning December 5, 1995, the expiration date of the '658 patent, well before the expiration date of the '431 patent in 2002. Glaxo filed this suit for patent infringement on November 13, 1991, alleging technical infringement of claims 1 and 2 of the '431 patent by the ANDA filing as provided in *35 U.S.C. § 271*(e)(2) (1988). Novopharm admitted infringement of the claims, but contended that the '431 patent was invalid because it was anticipated by the disclosure of the '658 patent.

Novopharm later amended its answer to add the defense of inequitable conduct arising from alleged false and misleading affidavits provided to the U.S. Patent and Trademark Office (PTO) during prosecution of the applications from which the '431 patent issued. Finally, on June 21, 1993, Novopharm sought summary judgment based on a third defense, Glaxo's alleged failure to disclose the best mode of practicing the claimed invention. The trial court denied the motion, and the case was tried to the court beginning on August 9, 1993.

On the question of anticipation, the court found that Novopharm had not carried its burden of proving by clear and convincing evidence that practice of Example 32 of the '658 patent **[**8]** always produced Form 2 ranitidine hydrochloride, so that Form 2 was not inherently disclosed by Example 32. As for inequitable conduct, the court agreed with Novopharm that the affidavits presented to the examiner were misleading and material, but it found that Novopharm had failed to prove any deceptive intent. The court also concluded that there was no violation of the best mode requirement because Novopharm had not proved that Crookes, the inventor, knew of the best mode, the statute and this court's precedent providing that knowledge by the inventor himself is required. Accordingly, the court held that the '431 patent was not invalid, was enforceable and infringed, and ordered that Novopharm refrain from commercial manufacture or sale of Form 2 ranitidine hydrochloride before the '431 patent expires. Novopharm appeals.

Discussion

I. Example 32, anticipation

We consider first Novopharm's argument that the district court erred in holding that Novopharm did not prove that the claims in suit of the '431 patent were anticipated by Example 32 of the '658 patent. Anticipation is a factual matter, which we review under the clearly erroneous standard. Diversitech **[**9]** *Corp. v. Century Steps Inc., 850 F.2d 675, 677, 7 U.S.P.Q.2D (BNA) 1315, 1317 (Fed. Cir. 1988).* A claim is anticipated and therefore invalid only when a single prior art reference discloses each and every limitation of the claim. *35 U.S.C. § 102*(a) (1988); *Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1571, 230 U.S.P.Q. (BNA) 81, 84 (Fed. Cir. 1986).* The disclosure need not be express, but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art. *Continental Can Co. USA Inc. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991).*

Novopharm maintains that the invention claimed in the '431 patent, ranitidine hydrochloride in its Form 2 crystalline polymorph, is inherently disclosed in the '658 patent because the practice of Example 32 always yields ranitidine hydrochloride in its Form 2 polymorph. Novopharm's experts performed the process disclosed in Example 32 of the '658 patent thirteen times and each time they made Form 2 crystals, not Form 1 as Glaxo claims.

But the district court found that the practice of Example 32 could yield crystals of either polymorph. It specifically found that Glaxo's David Collin originally made **[**10]** Form 1 by practicing Example 32, and that Glaxo's expert, Nicholas Crouch, did too. n4 We are not persuaded that these findings are clearly **[*1048]** erroneous. The district court correctly rejected the anticipation defense.

n4 Novopharm suggests that the court was wrong in finding that these experiments were within the scope of Example 32 because they employed procedures that sometimes departed from the strict letter of Example 32. The district court found that one skilled in the art would understand that these procedures were consistent with the teaching of Example 32. We do not see where the court erred in this finding.

II. Inequitable Conduct

Novopharm contends that the trial court erred as a matter of law in declining to infer an intent to deceive from Glaxo's material misrepresentations to the PTO. The charge of inequitable conduct arises from a declaration submitted by John Harold Hunt, the head of Glaxo's spectroscopy group, in response to a rejection in light of the product of Example 32 of the '658 **[**11]** patent. n5

n5 The case was complicated by the trial court's inability to hear testimony from Hunt due to his death in 1985.

To prevail on its inequitable conduct defense, Novopharm had to show by clear and convincing evidence that Glaxo misrepresented facts to the PTO during prosecution of the '431 patent, that the misrepresentation was material, and that Glaxo acted with the intent to deceive the PTO. *Kingsdown Medical Consultants Ltd. v. Hollister Inc., 863 F.2d 867, 872, 9 U.S.P.Q.2D (BNA) 1384, 1389 (Fed. Cir. 1988).* We review the district court's ultimate determination for abuse of discretion; the subsidiary factual questions of whether there was a misrepresentation, its materiality, and intent to deceive are reviewed for clear error. *Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1215, 18 U.S.P.Q.2D (BNA) 1016, 1028* (Fed. Cir.), cert. denied, *502 U.S. 856 (1991).*

On August 28, 1983, the examiner rejected claims 1 and 2 of Glaxo's Form 2 ranitidine hydrochloride patent application as anticipated by or **[**12]** obvious in light of the disclosure of the '658 patent. Glaxo argued that its claims were drawn to a specific crystalline form of ranitidine hydrochloride different from the compound disclosed in the '658 patent. The examiner asked for a showing that the claimed Form 2 ranitidine hydrochloride was patentably distinct from the prior art composition.

To overcome the rejection, Glaxo submitted Hunt's declaration comparing the IR spectra and x-ray powder diffraction patterns of the two crystalline forms. The declaration concluded that there were significant differences between the two products; a second declaration attested to the practical differences between the two polymorphs that made the Form 2 ranitidine hydrochloride preferable for commercialization.

Intent is often inferred from surrounding circumstances when a material misrepresentation is shown. *Paragon Podiatry Lab. v. KLM Lab., 984 F.2d 1182, 1189, 25 U.S.P.Q.2D (BNA) 1561, 1567 (Fed. Cir. 1993).* But an inference is not required in every case, even when the misrepresentation is in affidavit form. Glaxo admits that the Form 1 data submitted with the Hunt declaration was not obtained from ranitidine hydrochloride prepared according **[**13]** to Example 32 of the '658 patent. The trial court concluded from this that the declaration was misleading, because it suggested falsely that the data had been obtained from the product of Example 32. The court also found that the misstatement was material. But it nevertheless concluded that an inference of fraudulent intent was unwarranted. We have not been persuaded otherwise.

The court found that as head of spectroscopy, Hunt was familiar with data obtained from Form 1 material, including that originally made by Collin according to Example 32. He knew that in each case the Form 1 data was different from that obtained for Form 2. The court found that there was no difference between the IR spectrum of the Form 1 hydrochloride obtained according to Example 32 and that obtained by other methods. Likewise, although the Example 32 material was never subjected to x-ray diffraction analysis, material produced by other methods yielded a consistent powder diffraction pattern that was different from that obtained from Form 2 crystals; this material exhibited an IR spectrum identical to that of the Example 32 material.

The trial court concluded that Hunt did not believe there were any differences **[**14]** between material produced using Example 32 and the material from which he obtained the **[*1049]** data analyzed in his declaration. Accordingly, the court found that Novopharm failed to carry its burden of proving intent to deceive by clear and convincing evidence. Although this conclusion is debatable, that is not sufficient reason to reverse in the absence of firm and definite belief that the district court erred.

III. Best Mode

Novopharm next asserts that Glaxo failed to disclose the best mode of practicing the invention, that is, the azeotroping process it uses to formulate the claimed Form 2 ranitidine hydrochloride into pharmaceutical compositions. The best mode defense arose little more than two months before trial just after Glaxo produced documents based on which Novopharm filed a motion for summary judgment of invalidity for failure to disclose the best mode. Less than a week before trial, the district court denied Novopharm's motion stating that "the court cannot hold as a matter of law that Dr. Crookes knew that the azeotroping process was the best mode of manufacturing ranitidine hydrochloride, and summary judgment must therefore be denied." *Glaxo, Inc. v. Novopharm* **[**15]** *Ltd., 830 F. Supp. 869, 871 (E.D.N.C. 1993).* The district court further stated that it reserved for trial "ruling on the question of whether and to what extent the knowledge of other Glaxo employees and agents may be imputed to Dr. Crookes for purposes of finding a best mode analysis [sic, violation]." Id.

At trial, Novopharm produced evidence that officials at Glaxo knew of the azeotroping process and considered it to be the best mode of making Form 2 ranitidine hydrochloride into a pharmaceutical composition. Novopharm argued in district court, as it does here, that the knowledge of the azeotroping process by Glaxo officials should be imputed to inventor Crookes for purposes of finding a best mode violation.

The trial court found Novopharm's argument to have some "intuitive appeal" since Glaxo "has enjoyed the monopoly the issued patent provides." *Glaxo, 830 F. Supp. 871, 881-82, 29 U.S.P.Q.2D (BNA) 1126, 1134*

(E.D.N.C. 1993). Indeed, the trial court stated that if it were to impute the knowledge of others to the inventor of the '431 patent, "then clearly the court would be required to find a best mode violation." *Id. at 882.* The trial court concluded, however, that the statute, **[**16]** *35 U.S.C. § 112,* first paragraph, and this court's holding in *Texas Instruments, Inc. v. United States International Trade Commission, 871 F.2d 1054, 10 U.S.P.Q.2D (BNA) 1257 (Fed. Cir. 1989)* do not permit using imputed knowledge in a best mode analysis. The district court concluded that Novopharm "as a matter of law . . . failed to show the '431 patent should be invalidated based on a best mode violation." *830 F. Supp. at 882.* On appeal, Novopharm asserts that the district court erred as a matter of law in holding that a best mode defense cannot be found in the absence of proof that the inventor knew of that mode.

The statutory provision at issue sets forth that:

> The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, first paragraph (1988).

The statutory language could not be clearer. The best mode of carrying out an invention, indeed if there is one, to be disclosed is that "contemplated by the inventor." That the best mode "belongs" to the inventor finds consistent support in previous statutory language as well. n6 Additionally, the commentary on the 1952 Patent Act states with respect **[**17]** to the best mode provision that "this requirement, it should be noted, is not absolute, since it only requires **[*1050]** disclosure of the best mode contemplated by the inventor, presumably at the time of filing the application." P.J. Federico, Commentary on the New Patent Act, *35 U.S.C.A. 1,* 25 (1954).

> n6 The 1793 Act stated: "in the case of any machine [the inventor] shall fully explain the principle, and the several modes in which he has contemplated the application of that principle or character, by which it may be distinguished from other inventions." Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318.
>
> The 1836 Act stated: "in case of any machine, [the inventor] shall fully explain the principle, and the several modes in which he has contemplated the application of the principle or character by which it may be distinguished from other inventions." Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117.
>
> The Act of 1870 changed the 'several modes' provision of the previous Acts to the present-day 'best mode.' Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198.

[18]**

In arguing that Glaxo did not comply with the best mode requirement of § 112, first paragraph, Novopharm relies on *Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 U.S.P.Q.2D (BNA) 1016* (Fed. Cir.), cert. denied, *502 U.S. 856 (1991),* for the proposition that the best mode requirement lies at the heart of the statutory quid pro quo of the patent system. This is true enough. However, Amgen, consistent with the statute, speaks of the best mode requirement in terms of the best mode contemplated by the inventor. *Amgen, 927 F.2d at 1210, 18 U.S.P.Q.2D (BNA) at 1024* ("Our case law has interpreted the best mode requirement to mean that there must be no concealment of a mode known by the inventor to be better than that which is disclosed.") (emphasis added). In fact, as we have previously stated, the sole purpose of the best mode requirement "is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived." *Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 926, 16 U.S.P.Q.2D (BNA) 1033, 1035 (Fed. Cir. 1990)* (emphasis added) (quoting *In re Gay, 50 C.C.P.A. 725, 309 F.2d 769, 772,* **[**19]** *135 U.S.P.Q. (BNA) 311, 315 (CCPA 1962));* see *Dana Corp. v. IPC Ltd. Partnership, 860 F.2d 415, 419, 8 U.S.P.Q.2D (BNA) 1692, 1696 (Fed. Cir. 1988),* cert. denied, *490 U.S. 1067, 104 L. Ed. 2d 633, 109 S. Ct. 2068 (1989).*

The best mode inquiry focuses on the inventor's state of mind at the time he filed his application, raising a subjective factual question. *Chemcast, 913 F.2d at 926, 16 U.S.P.Q.2D (BNA) at 1035.* The specificity of disclosure required to comply with the best mode requirement must be determined by the knowledge of facts within the possession of the inventor at the time of filing the application. *Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535, 3 U.S.P.Q.2D (BNA) 1737, 1745* (Fed. Cir.), cert. denied, *484 U.S. 954, 98 L. Ed. 2d 372, 108 S. Ct. 346 (1987).* That the best mode inquiry is grounded in knowledge of the inventor is even more evident upon contrasting the best mode requirement of § 112 with the enablement requirement of that section. *Chemcast, 913 F.2d at 926, 16 U.S.P.Q.2D (BNA) at 1035.* "Enablement looks to placing the subject matter of the claims generally in the possession of the public." *Spectra-Physics, 827 F.2d at 1532, 3 U.S.P.Q.2D (BNA) 1742.* Best mode looks to whether specific instrumentalities and techniques have been developed **[**20]** by the inventor and known to him at the time of filing as the best way of car-

rying out the invention. Id.; *Chemcast, 913 F.2d at 927-28, 16 U.S.P.Q.2D (BNA) at 1036.* The enablement requirement, thus, looks to the objective knowledge of one of ordinary skill in the art, while the best mode inquiry is a subjective, factual one, looking to the state of the mind of the inventor. Indeed, recently this court in addressing whether an applicant's best mode had to be updated upon filing a continuation application affirmed that the best mode requirement "focuses on what the inventor knows." *Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 558, 32 U.S.P.Q.2D (BNA) 1077, 1083 (Fed. Cir. 1994)* (emphasis added), cert. denied, *130 L. Ed. 2d 1069, 115 S. Ct. 1102 (1995).*

Based on the clear wording of the statute and our case law, the trial court properly rejected Novopharm's "imputed knowledge"

best mode defense. As the trial court correctly noted, we held in Texas Instruments that there was no violation of the best mode requirement of § 112 by reason of knowledge of the purported best mode on the part of T.I. employees, other than the inventor, in the manufacturing group when the inventor **[**21]** did not know of or conceal this best mode. *Texas Instruments, 871 F.2d at 1061, 10 U.S.P.Q.2D (BNA) at 1262.*

There is simply no evidence in the record before us, indeed Novopharm points to none, that the inventor of the '431 patent knew of and concealed the azeotroping process when his application was filed. Inventor Crookes in a declaration in opposition to Novopharm's best mode summary judgment motion stated "I did not know of any azeotroping of ranitidine hydrochloride, or of its benefits, prior to **[*1051]** commencement of this litigation. I did not -- indeed, could not -- consider the azeotrope process a 'best mode' of making ranitidine hydrochloride tablets at the time of filing any patent application." Crookes indicated that he worked in a different department than those who developed the azeotroping process.

As the district court observed, the record does indicate, however, that others at Glaxo knew of the azeotroping process and knew that this process would be used commercially to produce pharmaceutical forms of the claimed product. n7 The record also indicates that these individuals as well as their English patent agent were concerned that failure to disclose the azeotroping process may **[**22]** present a best mode problem. However, in neither instance did Glaxo nor its patent agent appropriately consider that inventor Crookes knew nothing of the azeotroping process. That Glaxo thought it may have a best mode problem either because of its incorrect or incomplete consideration of U.S. patent law does not make it so.

n7 The claims at issue are not directed to a pharmaceutical compound. Therefore, there may be a question whether the azeotroping process is indeed the best mode of carrying out the claimed invention. See *Chemcast, 913 F.2d at 927, 16 U.S.P.Q.2D (BNA) at 1036.* In view of our decision, however, it is not necessary for us to reach this issue.

Novopharm maintains that Glaxo intentionally isolated Crookes from knowledge of the azeotroping process leaving "it to others to commercialize and reduce the invention to practice." Thus, Novopharm fears that Glaxo purposefully prevented the inventor from gaining knowledge of the most advantageous application for his invention, the azeotroping process, so **[**23]** that that process could be maintained as a trade secret. That fear does not equate with a best mode violation.

In this case, Crookes was unconcerned with the commercialization of the claimed compound. It is undisputed that Crookes invented a compound and was not involved in whatever processes were to be used to commercially produce it. Therefore, whether Glaxo deliberately walled off the inventor is irrelevant to the issue of failure of his application to disclose the best mode known to him.

In arguing that Crookes was screened from knowledge, Novopharm relies on testimony of Glaxo's in-house patent agent that Crookes was not consulted "at any time" during the preparation of the application that matured into the '431 patent. This however, completely ignores the **requirement** that patents are applied for "in the name of the actual inventor or inventors" according to 37 C.F.R. § 1.41(a) (1983). The inventor(s) must submit an oath or declaration attesting that they have "reviewed and understand[] the contents of the specification" and believe "the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which **[**24]** a patent is sought." 37 C.F.R. § 1.63(b)(1), (2) (1992); see also 37 C.F.R. § 1.51(a)(2) (1992). Moreover, this court in *Sun Studs, Inc. v. Applied Theory Associates, Inc., 772 F.2d 1557, 1568, 227 U.S.P.Q. (BNA) 81, 89 (Fed. Cir. 1985),* recognized that *35 U.S.C. § 111* (1988) "requires that the inventor must apply for the patent." *Sun Studs, 772 F.2d at 1568, 227 U.S.P.Q. (BNA) at 89* (emphasis in original). Novopharm has not alleged that these requirements were violated.

It is therefore presumed that Crookes, the inventor and applicant, must have reviewed the specification and signed the required declaration before the application was filed. Without more, Novopharm is simply wrong when it alleges that Crookes had nothing to do with de-

termining what needed to be disclosed in his patent application.

Novopharm additionally contends that looking solely to the inventor's knowledge in a best mode analysis "makes a mockery of the best mode requirement, and fosters a 'head in the sand' mentality for corporate applicants."

However, the practical reality is that inventors in most every corporate scenario cannot know all of the technology in which their employers are engaged. Therefore, whether **[**25]** intentionally or not, inventors will be effectively isolated from research no matter how relevant it is to the field in which they are **[*1052]** working. Separating scenarios in which employers unintentionally isolate inventors from relevant research from instances in which employers deliberately set out to screen inventors from research, and finding a best mode violation in the latter case, would ignore the very words of § 112, first paragraph, and the case law as it has developed, which consistently has analyzed the best mode requirement in terms of knowledge of and concealment by the inventor. Congress was aware of the differences between inventors and assignees, see *35 U.S.C. § § 100*(d) and 152, and it specifically limited the best mode required to that contemplated by the inventor. We have no authority to extend the requirement beyond the limits set by Congress.

The dissent argues that imputing knowledge of others than the inventor to the inventor for purposes of considering what was "contemplated by the inventor" in a best mode analysis "may be necessary under appropriate circumstances, to protect the public's 'paramount interest in seeing that patent monopolies spring from backgrounds **[**26]** free from fraud or other inequitable conduct.'" The dissent contends that such knowledge can be imputed to the inventor under principles of agency law stating that, "an agent's acts and knowledge can be imputed to the principal when necessary to protect the interests of others, so long as the acts or knowledge in question fall within the scope of the agent's authority," citing Restatement (Second) of Agency, § 261.

The Restatement defines agency as "the fiduciary relation which results from the manifestation of consent by one person to another that the other shall act on his behalf and subject to his control, and consent, by the other so to act." Restatement (Second) of Agency, § 1.

The flaw in the dissent's analysis is that a patent attorney n8 does not enter into an agency relationship with the inventor for purposes of what is disclosed in the inventor's patent application. Simply, the inventor never authorizes his patent attorney to "act on his behalf" with respect to disclosing the invention. Or, in the terms used by the dissent, the scope of the patent attorney's authority does not include inventing, i.e., either supplementing or supplanting the inventor's knowledge of his **[**27]** own invention. Rather, the information disclosed in the inventor's patent application must be that which is actually known to him. The statute requires that he submit an oath to this effect. See *35 U.S.C. § 115* (1988).

> n8 A "patent agent" is subsumed within this term as a patent agent acts as the inventor's attorney before the PTO. The label "patent agent" does not mean there is an agency relationship, rather than an attorney-client relationship, between the inventor and such individual for all purposes.

An agency relationship may exist during prosecution before the PTO where the patent attorney is acting on the inventor's behalf. See 37 C.F.R. 1.56(a) (1992). An agency relationship does not exist, however, with respect to what an inventor must disclose in order to obtain a patent on his invention, which includes, of course, any best mode under § 112. Therefore, in addition to being inconsistent with § 112, as explained above, because an agency relationship does not exist for purposes of what is **[**28]** disclosed in a patent application, it would be improper to impute a patent attorney's knowledge of a best mode to the inventor for purposes of finding a best mode violation.

In any case, the dissent's application of general agency principles to the analysis of best mode disclosure under § 112 is an entirely new idea and is not existing law.

The trial court here correctly noted that this court has "found that the absence of a showing of actual knowledge by the inventor was dispositive of the defendant's best mode argument" and held that the law "does not permit using imputed knowledge" in a best mode defense. *Glaxo, 830 F. Supp. at 881-82, 29 U.S.P.Q.2D (BNA) at 1135* (emphasis added). The district court therefore correctly rejected the best mode defense.

IV. Conclusion

Accordingly, the judgment of the United States District Court for the Eastern District of North Carolina is affirmed.

AFFIRMED

DISSENTBY: MAYER

DISSENT: **[*1053]** MAYER, Circuit Judge, dissenting.

With this case, the court blesses corporate shell games resulting from organizational gerrymandering and willful ignorance by which one can secure the monopoly of a patent while hiding the best mode of practicing **[**29]** the invention the law expects to be made public in return for its protection. Because I believe this is a perverse interpretation of the law, I dissent.

The best mode requirement arises from the first paragraph of *35 U.S.C. § 112* (1988), which provides that the patent specification "shall set forth the best mode contemplated by the inventor of carrying out his invention." The best mode inquiry is twofold: first, did the inventor know of a preferred mode or embodiment of the invention; and second, did the inventor disclose that mode sufficiently to allow those skilled in the art to practice it. *Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 928, 16 U.S.P.Q.2D (BNA) 1033, 1036 (Fed. Cir. 1990).* The first question is largely subjective, looking to the inventor's knowledge and belief. The second is more objective, focusing on the scope of the invention and the level of skill in the art. Id. Compliance with the best mode requirement is a factual question, which we review for clear error. *Engel Indus. Inc. v. Lockformer Co., 946 F.2d 1528, 1531, 20 U.S.P.Q.2D (BNA) 1300, 1302 (Fed. Cir. 1991).* But this assumes a correct understanding of the relevant law, which we review de novo. See Spectra-Physics, **[**30]** *Inc. v. Coherent, Inc., 827 F.2d 1524, 1536, 3 U.S.P.Q.2D (BNA) 1737, 1745 (Fed. Cir. 1987).*

Novopharm says Glaxo did not disclose the best mode of practicing the invention -- the azeotropic granulation process it used to formulate ranitidine hydrochloride into pharmaceutical compositions. This defense became relevant only late in the game when, on June 2, 1993, Glaxo produced some documents that indicated that it had withheld information about the granulation process. Novopharm moved for summary judgment based on the best mode violation, which the district court denied, *Glaxo, Inc. v. Novopharm Ltd., 830 F. Supp. 869 (E.D.N.C. 1993),* but allowed Novopharm to present the best mode defense at trial. Novopharm tried to take discovery on the issue, including a deposition of Crookes, the named inventor of the '431 patent, and Collin, his immediate supervisor. After Glaxo resisted and sought a protective order, the district court denied Novopharm any discovery, and the case proceeded to trial on August 9, 1993. At the close of Novopharm's case-in-chief on its best mode defense, the court decided to rule on that question as a matter of law, no factual issues remaining. Glaxo presented no evidence **[**31]** on the issue. The court held that because Crookes had no personal knowledge of the best mode, there was no requirement that it be disclosed.

Glaxo first suggests that the azeotropic granulation process was not an appropriate candidate for disclosure because it fell outside the scope of the claimed invention. Rather, Glaxo says the process is simply a production technique useful in the formulation of ranitidine hydrochloride into pharmaceutical compositions. It says the process is therefore relevant, if at all, only to the claims of the '431 patent that cover such compositions. No such claims are at issue here, so Glaxo says the best mode should not be considered.

But the statutory language demands that the patent disclose the best mode of "carrying out" the claimed invention. As the district court recognized, this language encompasses not only modes of making the invention, but of using it as well. See *Christianson v. Colt Indus. Operating Corp., 822 F.2d 1544, 1563, 3 U.S.P.Q.2D (BNA) 1241, 1255 (Fed. Cir. 1987),* vacated on other grounds, *486 U.S. 800 (1988).* The azeotroping process was the best way to formulate raw ranitidine hydrochloride into pharmaceutical compositions suitable **[**32]** for use as a drug in human patients, the only use Glaxo contemplated for the invention. Glaxo admits the process was not generally known to those skilled in the art. Accordingly, the court could have found that disclosure of the process was required by section 112, so long as the other, subjective, elements of the best mode test were met. Cf. *Chemcast, 913 F.2d at 930, 16 U.S.P.Q.2D (BNA) at 1038* ("Whether characterizable as 'manufacturing data,' 'customer requirements,' or even 'trade secrets,' information necessary to practice the best mode simply must be disclosed.").

[*1054] The best mode inquiry begins with what the inventor knew when he filed his application. This subjective part of the inquiry traditionally rests on the factual question whether the inventor actually contemplated a preferred mode. *Chemcast, 913 F.2d at 928, 16 U.S.P.Q.2D (BNA) at 1036.* But the inquiry is not limited to the inventor's actual knowledge.

The court believes *Texas Instruments, Inc. v. United States International Trade Commission, 871 F.2d 1054, 10 U.S.P.Q.2D (BNA) 1257 (Fed. Cir. 1989),* expressly limited best mode to the inventor's actual knowledge, but that case includes no such limitation. We merely agreed with the Commission **[**33]** that Texas Instrument's computer component patents were not invalid for failure to disclose the alleged best mode, a so-called "word boost" feature, because "'the record does not disclose that the applicant knew of or concealed a better mode than he disclosed.'" *871 F.2d at 1061, 10 U.S.P.Q.2D (BNA) at 1262* (quoting Commission findings).

The problem arises from reading one sentence of the Texas Instruments opinion out of context. We said that "the fact that Texas Instruments may have manufactured

a DRAM containing a different or better form of boosting means is not pertinent to whether the specification disclosed" the best mode known to the inventors. Id. The court reads this to parallel the facts of our case -- that the employer of the named inventors developed the alleged best mode wholly without the inventors' knowledge, and that there was no best mode problem because the inventors did not know of it.

But as our opinion in Texas Instruments shows, the inventors did know of the word boost feature, but did not believe that it was part of the best mode. Id. ("That the inventors themselves did not consider the 'word boost' feature to be part of the best mode of their invention **[**34]** refutes any argument that the inventor 'knew of and concealed a better mode than he disclosed.'"). Accordingly, Texas Instruments stands only for the unremarkable proposition that there is no best mode violation where the inventor knew of the alleged mode and did not consider it to be a part of the preferred embodiment. It says nothing about whether specific knowledge of a best mode by a corporate assignee/employer may be imputed to the inventor/employee. Nor does any other precedent of this court.

As the district court recognized, "Glaxo, and not Crookes individually, . . . both directed the patent prosecution and has enjoyed the monopoly the issued patent provides." *830 F. Supp. at 881-82.* Glaxo employees acted as agents for inventor Crookes during prosecution of the U.S. application. They were also agents for Glaxo, the assignee of the application and later the owner of the '431 patent. And that is the crucial point: Glaxo, not Crookes, brought this suit against Novopharm for infringement of the patent. Accordingly, Glaxo's conduct and knowledge during prosecution is important to the resolution of this case; it is not irrelevant, as the court says.

Glaxo says, and the court **[**35]** agrees, that it did not have to disclose the azeotroping process because Crookes did not know of that method of preparing pharmaceutical compositions of Form 2 ranitidine hydrochloride. On the record before us, one wonders how Glaxo could have been sure of what Crookes knew. Brereton, the Glaxo employee charged with initiating the application for the '431 patent, testified that he did not consult Crookes, the named inventor, at any time. Instead, in accordance with Glaxo's standard patent policy, Brereton conferred with Crookes' superiors to obtain all of the information necessary to secure a patent on the invention. It strikes me as incongruous to rely on the inventor's actual knowledge here if Glaxo indeed thought that knowledge was so insignificant that it did not even merit consultation during preparation of the application. * At the very least, the district court **[*1055]** should have given Novopharm the chance at discovery about just what Crookes in fact knew.

> * The court finds comfort in the regulations requiring that the inventor sign an oath attesting that he has reviewed the application, 37 C.F.R. § § 1.41(a), 1.51(a)(2) & 1.63(b)(1)(2), reasoning that Glaxo must have at least let Crookes review the application before it was filed. But none of these regulations speaks to the best mode requirement. Nor are we told how Crookes could sign such an oath if he was never consulted before the application was filed. Perhaps the court has hit upon grounds for a charge of inequitable conduct against Glaxo that everyone else missed.

[36]**

But I believe that even absent further discovery the district court could have found a best mode violation in this case. As the district court stated,

> it is undisputed, however, Brereton and other officers within Glaxo believed azeotroping was the best mode of preparing ranitidine hydrochloride for pharmaceutical use, and Glaxo actually utilized this method in the commercial production of ranitidine hydrochloride. These officials within Glaxo made a deliberate choice not to reveal what they believed to be the best mode of making the patented invention, but instead to protect the knowledge as a trade secret.

830 F. Supp. at 881. This recitation suggests that Glaxo set out to isolate Crookes from any knowledge about the azeotroping technique specifically to avoid the best mode disclosure requirements. If true, these circumstances would justify imputing knowledge to Crookes from Brereton and the other Glaxo employees who acted as agents for Crookes during the application process. I would remand to allow the district court to make the necessary factual findings and decide whether to impute that knowledge.

Imputing knowledge to an inventor may be necessary under appropriate **[**37]** circumstances, to protect the public's "paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct." *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 816, 89 L. Ed. 1381, 65 S. Ct. 993 (1945)* (endors-

ing equitable doctrine of unclean hands in patent suits). "The possession and assertion of patent rights are 'issues of great moment to the public.'" *Id. at 815.* And the best mode requirement lies at the heart of this public interest. It is a vital part of the statutory quid pro quo that justifies a patent. *Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1210, 18 U.S.P.Q.2D (BNA) 1016, 1024 (Fed. Cir. 1991).* In return for a seventeen year monopoly the patentee must disclose his invention to the public. But he must go beyond simply informing the public of the bare outlines of the invention. He must also tell what he believes to be the best embodiment of the invention, and he must do so in a way that allows the public to practice that embodiment. This prevents the inventor from obtaining patent protection with a minimal disclosure that reveals only inferior forms of the invention, while retaining for himself the **[**38]** most advantageous modes of carrying the invention into practice. *In re Gay, 50 C.C.P.A. 725, 309 F.2d 769, 772, 135 U.S.P.Q. (BNA) 311, 315 (CCPA 1962).* The court's pinched reading of the best mode requirement surely violates at least the spirit of this rule at the public's expense.

Imputing an agent's knowledge to the principal has sound roots in law and equity. An agent's acts and knowledge can be imputed to the principal when necessary to protect the interests of others, so long as the acts or knowledge in question fall within the scope of the agent's authority. Restatement (Second) of Agency, § 261 (principal liable for agent's fraud within scope of agency), § 274 (knowledge of agent acquiring property for principal imputed to principal); see also *American Soc. of Mechanical Engineers, Inc. v. Hydrolevel Corp., 456 U.S. 556, 566, 72 L. Ed. 2d 330, 102 S. Ct. 1935 (1982)* (principal liable for antitrust violation based on agent's fraud within apparent authority). This precept is firmly rooted in patent law as well, in the traditional doctrine of inequitable conduct, whereby the inventor's duty to disclose material information to the Patent Office is extended to all those involved in the filing and prosecution of a patent application. **[**39]** See 37 C.F.R. § 1.56 (1994); *Fox Indus. v. Structural Preservation Sys., 922 F.2d 801, 804, 17 U.S.P.Q.2D (BNA) 1579, 1581 (Fed. Cir. 1990).*

The fact that Crookes' agents knew about the process does not by itself justify imputing that knowledge to him. If he really was unfamiliar with the azeotroping process, that unfamiliarity may simply have resulted from the normal division of labor necessary within a large corporate enterprise. But the district court appears to have inferred a darker subtext -- that Glaxo may have deliberately **[*1056]** set out to screen this inventor from the azeotroping technique to conceal the process for itself.

The problem is that Glaxo's version of best mode, which the court now adopts, would allow, if not encourage, employers to isolate their employee/inventors from research directed to finding the most advantageous applications for their inventions, knowledge that the inventors would probably have had but for the employer's efforts to keep the work secret. As a result, inventors may have only limited perspective on the real value of their inventions, and can accordingly share only this limited perspective with the public. All the while, the employer/assignee will **[**40]** have a view of the big picture, fully aware, through its other employees, of superior modes of practicing the invention. But the assignee will be under no obligation to disclose those modes to the public. This deliberate subversion of the statutory disclosure would deprive the public of the benefits of the best mode of practicing the invention. There is no reason why this court should condone such abuse of the public trust. Cf. *Precision Instrument Co., 324 U.S. at 815.*

I would hold that if there truly was such a pattern of deliberate concealment of information that would otherwise have been known to the inventor, the knowledge of those who sought to conceal that information and who now attempt to enforce the patent may be imputed to the inventor. The district court can refuse to enforce the patent and should be given the opportunity to do so with a correct understanding of its powers.